

Aqualarm; Civigel; Gel-Larmes; Lacrinorm; Lacryvis; Liposis; Siccalfuid; **Ger.**: Anufil G; Liposis; Liqueigel; Siccacos; Thilo-Tears; Vidisic; Visc-Optal; **Gr.**: Dacrio Gel; Liposis; Tear-drops; Thilogel; Viscote; **Hong Kong:** Lacryvis; Liposis; Viscotears; **Hung.**: Oftagel; Vidisic; **Ir.**: GelTears; Liquevis; Vidisic; **Israel:** Viscotears; **Ital.**: Dacriogel; Droggel; Lacrijet; Lacrinorm; Lipovis; Siccalfuid; Viscotears; **Malaysia:** Vidisic; **Mex.**: Conforjel; Lacryvis; Lipolac; Refresh; Viscotears; **Neth.**: Dry Eye Gel; Lacrinorm; Liposis; Siccalfuid; Thilo-Tears; Vidisic; **Norw.**: Oftagel; Viscotears; **NZ:** Viscotears; **Philipp.**: Lacryvis; Lipolin; Siccalfuid; Vidisic; **Pol.**: Oftagel; Oftipan; Vidisic; **Port.**: Lacryvis; Liposis; Siccalfuid; Vidisic; **Rus.**: Oftagel (Офтрагель); Vidisic (Видисик); **S.Afr.**: Teargel; **Singapore:** Lacryvis; Vidisic; **Spain:** Lacryvis; Lipolac; Siccalfuid; Viscotears; **Swed.**: Oftagel; Viscotears; **Switz.**: Lacrinorm; Lacryvis; Siccalfuid; Viscotears; **Thai:**: Lacryvis; Vidisic; **Turk.**: Lacryvis; Siccapos; Thilo-Tears; Viscotears; **UK:** GelTears; Liposis; Liquevis; Viscotears; **Venez.**: Acrylarm; Lacryvis; Siccalfuid; Viscotears.

**Multi-ingredient:** **Arg.**: Lattas; **Austral.**: Gental Moisturising; **Chile:** Gelsollets; **Cz.**: Hypotears; **Hong Kong:** Clinac OC; Hypotears; **Indon.**: Gental; Oculotect; **Ir.**: Liposis; **Ital.**: Droyal; **Pol.**: Oculotect; **Port.**: Hidratante VG; **Switz.**: Lacrycon; **USA:** Maxilube; **Venez.**: Gental.

## Carmellose (rINN)

Carboxymethylcellulose; Carmellosum; Carmelosa; CMC; E466.

Кармеллоза

CAS — 9000-11-7.

**Pharmacopoeias.** In *Jpn*.

## Carmellose Calcium (rINNM)

Calcii Carmellosum; Calcium Carboxymethylcellulose; Carboxymethylcellulose Calcium; Carmellose calcique; Carmellosum calcium; Carmellosum Calcium; Carmelosa cálcica; Karmelozés kalcio druska; Karmellosalkáium; Karmelloskalcium; Karmeloz-kalcium; Karmelosa vápenatá sül.

Кальций Кармеллоза

CAS — 9050-04-8.

**Pharmacopoeias.** In *Eur.* (see p.vii) and *Jpn*. Also in *USNF*.

**Ph. Eur. 6.2** (Carmellose Calcium). A white or yellowish-white, hygroscopic powder. It swells in water to form a suspension; practically insoluble in alcohol, in acetone, and in toluene. Store in airtight containers.

**USNF 26** (Carboxymethylcellulose Calcium). A white to yellowish-white, hygroscopic powder. It swells in water to form a suspension; practically insoluble in alcohol, in acetone, in chloroform, in ether, and in benzene. pH of a 1% suspension in water is between 4.5 and 6.0. Store in airtight containers.

## Carmellose Sodium (BAN, rINNM)

Carboxymethylcellulose Sodium; Carboxymethylcellulosum Natrium; Carmellose sodique; Carmellosum natrium; Carmelosa sódica; Cellulose Gum; E466; Karmelozés natrio druska; Karmellosinatium; Karmellosnatrium; Karmeloz-nátrium; Karmelosa sodná sül; Karmelozá sodová; Natrii Carmellosum; SCMC; Sodium Carboxymethylcellulose; Sodium Cellulose Glycollate.

Натрий Кармеллоза

CAS — 9004-32-4.

**Pharmacopoeias.** In *Eur.* (see p.vii), *Int.*, *Jpn*, and *US*.

*Eur.* and *USNF* also include low-substituted carmellose sodium. *USNF* also includes Carboxymethylcellulose Sodium 12.

*Eur.* also includes a mixture of microcrystalline cellulose with carmellose sodium.

**Ph. Eur. 6.2** (Carmellose Sodium). A white or almost white, hygroscopic granular powder. It has a sodium content of 6.5 to 10.8% calculated on the dry substance. Easily dispersed in water forming colloidal solutions; practically insoluble in dehydrated alcohol, in acetone, in ether, and in toluene. A 1% colloidal solution in water has a pH of 6.0 to 8.0.

**Ph. Eur. 6.2** (Carmellose Sodium, Low-substituted; Carmellosum Natrium, Substitutum Humile). It contains not less than 2.0% and not more than 4.5% of sodium, calculated with reference to the dried substance. A white or almost white powder or short fibres. It swells in water to form a gel; practically insoluble in dehydrated alcohol, in acetone, and in toluene. A 1% suspension in water has a pH of 6.0 to 8.5.

**Ph. Eur. 6.2** (Microcrystalline Cellulose and Carmellose Sodium). A colloid-forming, powdered mixture of microcrystalline cellulose with 5 to 22% of carmellose sodium. It contains 75 to 125% of the nominal amount of carmellose sodium, calculated with reference to the dried substance. A white or off-white, coarse or fine powder. Dispersible in water producing a white, opaque colloidal dispersion; practically insoluble in organic solvents and in dilute acids. pH of a 2% dispersion in water is 6 to 8.

**USP 31** (Carboxymethylcellulose Sodium). A white to cream-coloured, hygroscopic powder or granules. It contains not less than 6.5% and not more than 9.5% of sodium, calculated on the dried basis. Easily dispersed in water to form colloidal solutions; insoluble in alcohol, in ether, and in most other organic solvents. pH of a 1% solution in water is between 6.5 and 8.5. Store in airtight containers.

**USNF 26** (Low-Substituted Carboxymethylcellulose Sodium). It has a sodium content of 2.0 to 4.5%, calculated on the dried basis. A white or almost white powder or short fibres. Practically insoluble in alcohol, in acetone, and in toluene. It swells in water

to form a gel. pH of a 1% suspension in water is between 6.0 and 8.5. Store in airtight containers.

**USNF 26** (Carboxymethylcellulose Sodium 12). A colourless or white to off-white, odourless, powder or granules. Water solubility depends on degree of substitution (easily dispersed in water at all temperatures, forming a clear, colloidal solution). Insoluble in alcohol, in acetone, in ether, and in toluene. It has a sodium content of 10.4 to 12.0%, calculated on the dry substance. Store in airtight containers.

**Incompatibility.** Incompatibilities of carmellose sodium have been reported with strongly acidic solutions, with soluble salts of iron and some other metals, and with xanthan gum.

## Croscarmellose Sodium (USAN)

Carmellosum natrium conexum; Croscarmellose sodique; Croscarmellose sódica; Crosslinked Carboxymethylcellulose Sodium; E468; Kroskarmelozés natrio druska; Kroskarmelloosi natrium; Kroskarmellosnatrium; Kroskarmelosa sodná sül; Kroskarmelozá sodová; Kroskarmeloz-nátrium; Modified Cellulose Gum.

**Pharmacopoeias.** In *Eur.* (see p.vii) and *Jpn*. Also in *USNF*.

**Ph. Eur. 6.2** (Croscarmellose Sodium). A cross-linked polymer of carmellose sodium. A white or greyish-white powder. Practically insoluble in dehydrated alcohol, in acetone, and in toluene. A 1% suspension in water has a pH of 5.0 to 7.0.

**USNF 26** (Croscarmellose Sodium). The sodium salt of a cross-linked partly *O*-(carboxymethylated) cellulose. A white, free-flowing powder. Partially soluble in water; insoluble in alcohol, in ether, and in other organic solvents. pH of a dispersion containing 1 g mixed with 100 mL of water for 5 minutes is between 5.0 and 7.0.

## Uses and Administration

Carmellose calcium and carmellose sodium have a variety of pharmaceutical uses, including use as suspending, thickening, and emulsifying agents, and as disintegrants, binders, and coating agents in tablets. Carmellose sodium is also used as an emulsifier or stabiliser in the food industry. Croscarmellose sodium is used as a tablet disintegrant.

Carmellose sodium is used typically as an ingredient of protective preparations for stoma care, in the management of wounds, and for the mechanical protection of oral and perioral lesions, such as mouth ulceration (p.1700). It is also used, in concentrations of up to 1%, in artificial saliva preparations for the treatment of dry mouth (p.2140), and in eye drops for the management of dry eye (p.2140).

Carmellose sodium given orally absorbs water and acts as a bulk-forming agent; the volume of faeces is increased and peristalsis promoted. It is used in the treatment of constipation (p.1693). Carmellose sodium has been included in preparations to control appetite in the management of obesity (p.2149) but there is little evidence of efficacy. For precautions to be observed with bulk-forming agents, see under Methylcellulose, p.2145.

## Preparations

**BP 2008:** Carmellose Sodium Eye Drops;

**USP 31:** Carboxymethylcellulose Sodium Paste; Carboxymethylcellulose Sodium Tablets.

**Proprietary Preparations** (details are given in Part 3)

**Arg.:** Aqua Lent Lagrima; Aqua Lent Lubricante; Aquecel; Aucic; Cellufresh; Celluvisc; Comfeel; Comfeel Plus Transparente; Natura Fresh; Nu-Derm Hidrocoloido; Refresh Liquegel; Refresh Tears; **Austral.:** Aquecel; Cellufresh; Celluvisc; Refresh Liquegel; Refresh Tears Plus; **Austria:** Celluvisc; **Belg.:** Gellifac; **Braz.:** Cellufresh; Ecofilm; Fresh Tears; Lacrifilm; Salivan; **Canad.:** Aquecel; Refresh Celluvisc; Refresh Liquegel; Refresh Plus; Refresh Tears; **Chile:** Refresh Liquegel; Refresh Tears; **Cz.:** Cellufresh; **Denm.:** Celluvisc; **Fin.:** Celluvisc; **Fr.:** Aquecel; Askina Biofilm; Biatini; Celluvisc; Clip Ampoules; Clip Brulures; Comfeel; Hydrocol; Physioutulle; Sureskin; Urgomed; Urgotul; **Ger.:** Algoplaque; Alione; Cellufresh; Cellumed; Celluvisc; Comfeel Plus Transparenter; Physioutulle; Urgotul; **Gr.:** Cellufresh; Celluvisc; **Hong Kong:** Refresh; **Ir.:** Celluvisc; **Israel:** Refresh Tears; **Ital.:** Cellufresh; Celluvisc; Lacriens; **Malaysia:** Refresh Plus; Refresh Tears; **Mex.:** Celluvisc; Novafix Ultra Fuerte; Refresh Liquegel; Refresh Tears; Thera Tears; **Neth.:** Celluvisc; **NZ:** Cellufresh; Celluvisc; Refresh Tears Plus; **Philipp.:** Cellufresh; Celluvisc; **Port.:** Aquecel; Askina Biofilm; Cellufresh; Celluvisc; **S.Afr.:** Cellufresh; Celluvisc; Comfeel; Refresh Liquegel; Refresh Tears; **Singapore:** Celluvisc; Refresh Plus; Refresh Tears; **Spain:** Cellufresh; Celluvisc; Viscofresh; **Swed.:** Celluvisc; **Switz.:** Cellufresh; Celluvisc; **Thai:** Cellufresh; Celluvisc; **UK:** Celluvisc; Comfeel; Intrastie; Physioutulle; **USA:** Celluvisc; Clear Eyes for Dry Eyes; Optive; Refresh Plus; Refresh Tears; Tears Again; TheraTears; **Venez.:** Refresh Liquegel; Refresh Tears.

**Multi-ingredient:** **Arg.:** Comfeel Plus; Comfeel Purilon; Comfeel Seasorb; Humectante Bucal; Mucobase; Purilon; Razagleda Plus; Seasorb; **Austral.:** Aque; Orabase; Orabase; SoloSite; Stomahesive; **Austria:** Glandosane; Sialin; **Braz.:** Chofranina; **Canad.:** Appedrine; Carboflex; Orabase; Orabase; Salivart; Tegassorb; **Chile:** Delgado Fibra; K.C.M.C.; Novafix Extra Fuerte; Reducform-F; Salivart; **Cz.:** Alginet; Spofax; **Fr.:** Altreet Ag; Amivia; Aquecel Ag; Artisial; Askina Sorbt; Biatini Argent; Cellosorb; Clip Hem; Intrasite; Melgisorb; Purilon; Release Ag; Seasorb; Urgosorb; Urgotul S.Ag; **Ger.:** Cellosorb; Comfeel Plus; Glandosane; Lary-Phary; Nu-Gel; Purilon; Rectal Algin; SeaSorb Soft; **Hong Kong:** Aque; Glandosane; **India:** Digene; **Ir.:** Orabase; **Israel:** Orabase; **Ital.:** Aquecel Ag; **NZ:** Orabase; Stomahesive; **Port.:** Askina Sorbt; Carboflex; Glandosane; Varihesive; **S.Afr.:** Granulox; Granugel; Orabase; **Spain:** Laxival; **Switz.:** Glandosane; **Thai:** Bisolax; Emulax; Glandosane; **UK:** Comfeel Plus; Glandosane; Luborant; Orabase; Orabase; Physioutulle-Ag; Seasorb Soft; Seprafilm; Stomahesive; **USA:** Entertainer's Secret; Moi-Stir; Prettis Diet Aid; Salivart; Seprafilm; Surgel; **Venez.:** Klincosal; Novafix; Polantac.

## Carrageenan

Carrageenanum; Carrageenin; Carragenina; Carraghenanes; Carraghenates; Chondrus Extract; E407; Irish Moss Extract.

CAS — 9000-07-1 (carrageenan); 11114-20-8 ( $\kappa$ -carrageenan); 9064-57-7 ( $\lambda$ -carrageenan).

**Pharmacopoeias.** In *Fr.* Also in *USNF*.

**USNF 26** (Carrageenan). The hydrocolloid obtained by extraction with water or aqueous alkali from some members of the class Rhodophyceae (red seaweeds). It consists chiefly of a mixture of the ammonium, calcium, magnesium, potassium, and sodium sulfate esters of galactose and 3,6-anhydrogalactose copolymers. The prevalent copolymers in the hydrocolloids are  $\kappa$ -carrageenan,  $\iota$ -carrageenan, and  $\lambda$ -carrageenan. A yellowish or tan to white, coarse to fine, practically odourless, powder. Soluble in water at 80° forming a viscous, clear or slightly opalescent solution that flows readily. It disperses more readily in water if first moistened with alcohol, with glycerol, or with a saturated solution of glucose in water. Store in airtight containers at a temperature of 8° to 15°.

## Uses and Administration

Carrageenan is used in pharmaceutical manufacturing and the food industry as a suspending and gelling agent. It has been used as a bulk-forming laxative to treat constipation; for precautions to be observed with bulk-forming laxatives, see under Methylcellulose, p.2145. Carrageenan is also included in topical preparations for the symptomatic relief of anorectal disorders. A gel containing carrageenan has been investigated as a topical microbicide.

A degraded form of carrageenan was formerly used in gastrointestinal disorders but it was associated with lesions in *animals* and is no longer used.

Irish moss (*Chondrus crispus*), a source of carrageenan, is used in herbal medicine.

◊ Refined non-degraded carrageenan and furcellaran, a similar extract from Rhodophyceae that is included in the specifications for food-grade carrageenan, have generally been considered safe for use as food additives, although this may not be the case with degraded and 'semi-refined' forms.<sup>1</sup> However, in the UK the Food Advisory Committee has recommended that carrageenan should not be permitted as an additive for infant formulas because of the possibility of immunological consequences after absorption from the immature gut.<sup>2</sup> Carrageenans affect the immune system of experimental *animals* after parenteral or oral use, and small amounts of food-grade carrageenan cross the intestinal epithelium in *rats* and are taken up by gut-associated lymphoid tissue.<sup>3</sup>

1. FAO/WHO. Evaluation of certain food additives and contaminants: twenty-eighth report of the joint FAO/WHO expert committee on food additives. *WHO Tech Rep Ser 710* 1984.

2. MAFF. Food Advisory Committee: report on the review of the use of additives in foods specially prepared for infants and young children. *FdAC/REP/12*. London: HMSO, 1992.

3. MAFF. Food Advisory Committee: report on the review of the emulsifiers and stabilisers in food regulations. *FdAC/REP/11*. London: HMSO, 1992.

**Preparations**

**Proprietary Preparations** (details are given in Part 3)

**Austria:** Coreine.

**Multi-ingredient:** **Austral.:** Bonningtons Irish Moss; **Austria:** Anoreine; Anoreine mit Lidocain; **Cz.:** Titanoreine; **Fr.:** Anoreine; Titanoreine; Titanoreine Lidocaine; **Ger.:** Saseem; **Ital.:** Resource Gellicata; **NZ:** Bonningtons Irish Moss; **Pol.:** Tytanoreina; **Spain:** Titanorein; **Switz.:** Giogeycl; Titanoreine; **UK:** Fam-Lax Senna.

## Cellacefate (BAN, rINN)

CAP; Celacefát; Celacefát; Celacefate; Celluliozós acetatas-ftalatas; Cellacéfate; Cellacéfatum; Cellacephate; Cellulosaacetatftalati; Cellulose, acétate phthalate de; Cellulose Acetate Phthalate; Cellulosa acetat phthalic; Cellulosum Acetylphthalicum; Cellulóz-acetát-ftalát; Celophthalmum; Selluloosa-asetatiftalaaatti.

Целлацефат

CAS — 9004-38-0.

**Pharmacopoeias.** In *Chin.*, *Eur.* (see p.vii), *Int.*, and *Jpn*. Also in *USNF*.

**Ph. Eur. 6.2** (Cellulose Acetate Phthalate; Cellacefate BP 2008). Cellulose in which some of the hydroxyl groups are acetylated (21.5 to 26.0%) and some are phthalylated (30.0 to 36.0%), both calculated with reference to the anhydrous, acid-free substance. A hygroscopic, white or almost white, free-flowing powder or colourless flakes. Practically insoluble in water, in dehydrated alcohol, and in dichloromethane; freely soluble in acetone; soluble in diethylene glycol; it dissolves in dilute solutions of alkalis. Store in airtight containers.

**USNF 26** (Cellacefate). A reaction product of phthalic anhydride and a partial acetate ester of cellulose. It contains 21.5 to 26.0% of acetyl groups, and 30.0 to 36.0% of phthalyl(*o*-car-